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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,457	04/14/2004	Chih-Ping Liu	55600-8014.US02	8343

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EXAMINER	
DANG, IAN D	
ART UNIT	**PAPER NUMBER**
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,457	LIU ET AL.	
	Examiner	Art Unit	
	Ian Dang	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :04/26/2006, 09/11/2006, 10/11/2006, 12/29/2006.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendments of 29 December 2006, 02 August 2004, 05 May 2004 have been entered in full.

Election/Restrictions

Applicant's election of species 1, an autoimmune disease, without traverse in the reply filed on 12/29/2007 is acknowledged. Claims 7-11 have been withdrawn. Claims 1-6 are pending and under examination.

Information disclosure statement

The information disclosure statements filed 4/26/2006 fails to comply with the provisions of 37CFR 1.97, 198 and MPEP 609 because the IDS of 4/26/2006 lists the first US Patent number as "R22". It has been placed in the application file, but the information referred to therein has not been considered as to the merits as, indicated. Applicant is advised that the date of any-resubmission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP 609.05(a).

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-

filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/219,128, and 09/910,406 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The claimed invention drawn to a method of preventing an increase in the blood level of IFN-gamma in a subject comprising orally administering interferon-tau (IFN-τ) to the subject at a dosage of greater than about 5x108 Units to decrease the subject's IFN-(γ) blood level relative to the IFN-γ blood level in the absence of IFN-γ administration. IFN-γ blood level in a subject are not disclosed in the provisional application 60/219,128 and application 09/910,406 but are disclosed in the provisional application 60/552,279 filed on 03/10/2004. Therefore claims 1-2, and 4-6 of the instant application receives the priority of the U.S. provisional application 60/552,279 with the filing date of 03/10/2004.

In addition, The amino acid sequences of the SEQ ID NO:2 and SEQ ID NO:3 are not disclosed in the U.S. provisional application 60/219,128 but are disclosed in U.S. application 09/910,406 now US Patent no 6,982,081 filed on 07/19/2001. Therefore, claim 3 of the instant application receives the priority of the U.S. application 09/910,406 filing date of 07/19/2001.

Foreign priority benefit

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Therefore, claim 3 of the instant application gets the priority of the U.S. application 09/910,406 filing date of 07/19/2001.

Specification

The disclosure is objected to because of the following informalities: Applicants need to update the status of the parent applications in the first line of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn a method of preventing an increase in the blood level of interferon-g in a subject at risk of an elevated IFN-g blood level due to administration of a therapeutic agent or a disease condition comprising orally administering interferon-tau to the subject at a dosage greater than about $5x10^8$ units to decrease the subjects INF-γ blood level relative to the IFN-g blood level in the absence of IFN-τ administration symptoms associated with an autoimmune disorder; claim 4 is drawn to a method wherein the subject has elevated IFN-γ level due to an autoimmune condition and orally administering continues during the period of the subject's symptoms. Thus, the claims are genus claims. The specification and claims do not indicate

what distinguishing attributes are shared by the members of the genus. Specifically, the specification does not clearly define IFN-τ, the subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-τ administration, a therapeutic agent, a disease condition, an autoimmune condition, and subject's symptoms and all methods of preventing a subject using such. Thus, the scope of the claims includes numerous structural and functional variants, and the genus' are highly variant because a significant number of structural and functional differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural and functional features that could distinguish IFN-τ, the subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-τ administration, a therapeutic agent, a disease condition, an autoimmune condition, and subject's symptoms are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, an IFN-τ, the subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-τ administration, a therapeutic agent, a disease condition, an autoimmune condition, and subject's symptoms are insufficient to describe the genus.

The written description requirement for a claimed genus' may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed

genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the genus for any IFN-τ, any subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-τ administration, any therapeutic agent, any disease condition, any autoimmune condition, and any subject's symptoms and all methods using such.

There is no description of the special features, which are critical to the structure and function of the genus claimed. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the IFN-τ, the subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-τ administration, the therapeutic agents, the disease conditions, the autoimmune conditions, and the subject's symptoms encompassed by the limitations. Thus, no identifying characteristics or properties of the IFN-τ, the subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-τ administrations, a therapeutic agent, a disease condition, an autoimmune condition, and subject's symptoms are provided such that one of skill would be able to predictably identify the encompassed by variant biological and chemical entities recited in the methods of the instant claims. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 112 (Enablement)

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a patient with multiple sclerosis by reducing the blood level of IFN-γ by administering the IFN-τ protein comprising the amino acid sequence of SEQ ID NO: 2 or 3, does not reasonably provide enablement for a method of preventing an

increase in the blood level of IFN-γ in a subject at risk of an elevated IFN-γ blood level due to (i) administration of a therapeutic agent or (ii) a disease condition, comprising orally administering IFN-τ to the subject at a dosage of greater than about $5x10^8$ units to decrease the subject's IFN-γ blood level relative to the IFN-g blood level in the absence of IFN-τ administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include: (1) Nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the breath of the claims, (7) the quantity of experimentation needed, (8) relative skill of those in the art.

Nature of the invention and breath of the claims

The claims are drawn to a method of preventing an increase in the blood level of IFN-γ in a subject at risk of an elevated IFN-γ blood level due to (i) administration of a therapeutic agent or (ii) a disease condition, comprising orally administering IFN-t to the subject at a dosage of greater than about $5x10^8$ units to decrease the subject's IFN-g blood level relative to the IFN-γ blood level in the absence of IFN-τ administration.

The invention is broad because the claimed prevention method encompass a large number of subjects, numerous therapeutic agents, numerous disease conditions, numerous symptoms, and numerous types of interferon-tau.

Unpredictability and state of the art

The state of the art for the role of interferon-tau during the pregnancy of ruminant animals and for treatment by administering ovine interferon-tau to the animal model for multiple sclerosis (MS) have been well characterized, but the state of the art for a method of preventing an increase in the blood level of IFN-γ in a subject at risk of an elevated IFN-γ blood level due to (i) administration of a therapeutic agent or (ii) a disease condition, comprising orally administering IFN-τ to the subject at a dosage of greater than about $5x10^8$ units to decrease the subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-t administration.

Soos et al. (2001) teach that interferon-tau is a type I interferon originally discovered for its role as pregnancy recognition hormone in ruminant animals such as sheep and cows. Interferon-tau possesses all the biological properties ascribed to the other type I interferons including antiviral, antiproliferative and immunomodulatory activities. However, interferon-tau differs in that it is relatively non-toxic to cells at high concentrations as compared to the toxicity normally associated with interferon alpha and beta and the type II interferon, interferon gamma (page 125, 1st paragraph).

Furthermore, Soos et al. (1995) teach that oral interferon-tau was effective in the prevention of both acute and relapsing experimental allergic encephalomyelitis (EAE), an animal model of the autoimmune disorder multiple sclerosis (MS) (page 2748, abstract). In addition, Soos et al. (2002) teach that oral interferon-tau was tested in phase I MS clinical trial. Studies have shown that interferon lacks toxicity and can be administered orally, and it considered an attractive candidate for evaluation in MS therapy (page 2231, column 2, 2nd paragraph).

In addition, the subject at risk disclosed in the specification (figure 2 and 5) already have an increase in the blood level of IFN-γ when administered IFN-τ. Consequently, IFN-τ cannot have any therapeutic role in preventing an increase in IFN-γ. While the method disclosed in the instant application is enabled for reducing IFN-g by administering IFN-τ, the claimed method supported in the specification is not predictive for a method of preventing an increase in the IFN-γ blood level in a subject.

Finally, the art is silent regarding subjects at risk with elevated IFN-γ blood level and the therapeutic role of interferon-tau in decrease the IFN-γ in subjects with elevated IFN-γ blood level due to the administration of a therapeutic agent or a disease condition. Thus one skilled in the art would not be able to predict that interferon-tau can be of therapeutic use to prevent an increase in the blood level of IFN-γ in a subject at risk. Undue experimentation would be required to determine such.

In view of these teachings, a method for treating a patient with multiple sclerosis by reducing the blood level of IFN-γ by administering IFN-t is not predictive for a method of preventing an increase in the blood level of IFN-γ in a subject at risk of an elevated IFN-γ blood level due to (i) administration of a therapeutic agent or (ii) a disease condition, comprising orally administering IFN-τ to the subject at a dosage of greater than about $5x10^8$ units to decrease the subject's IFN-γ blood level relative to the IFN-g blood level in the absence of IFN-τ administration.

The amount of direction or guidance present

Applicants' disclosure is limited to a method for administering IFN-τ to a patient with multiple sclerosis by reducing the level of IFN-γ. The specification does not provide guidance or

direction regarding identifying characteristics for risk associated with a subject, the therapeutic agent, disease condition, the subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-τ administration, the subject's symptoms, or the period time of the treatment during the subject's symptoms. In addition, the specification does not provide any guidance regarding the length of the treatment, the level constituting elevated level of IFN-γ, and the patient population at risk with elevated IFN-γ blood level.

Also, regarding the numerous forms of IFN-τ encompassed by the claims, the specification broadly teaches that interferon-tau "refers to any one of a family of interferon proteins having at least one characteristic from each of the following two groups of characteristics: (i) (a) anti-luteolytic properties, (b) anti-viral properties, (c) anti-cellular proliferation properties; and (ii) about 45 to 68% amino acid homology with α-interferons and greater than 70% amino acid homology to known IFNτ sequences" (page 7, [0038]).

Working Examples

Although Applicants have provided examples for treating a patient with multiple sclerosis by reducing the level of IFN-γ in the blood by administering IFN-τ (Figure 2 and 5, paragraphs 65-67), the specification does not provide any example for a method of completely preventing an increase in the blood level of IFN-γ in a subject at risk of an elevated IFN-γ blood level due to (i) administration of a therapeutic agent or (ii) a disease condition, comprising orally administering IFN-τ to the subject at a dosage of greater than about $5x10^8$ units to decrease the subject's IFN-g blood level relative to the IFN-g blood level in the absence of IFN-τ administration.

In addition, there are no examples for preventing increases in IFN-γ blood level due to the administration of a therapeutic agent or a disease condition by orally administering IFN-τ. method of treatment of an autoimmune disease besides multiple sclerosis, because the subjects tested have already elevated level of IFN-γ.

The quantity of experimentation needed

Without sufficient disclosure in the specification, it would require undue experimentation for one of skill in the art to able to prevent an increase in the blood level of IFN-τ in a subject at risk due to administration of a therapeutic agent or a disease condition. In addition, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims, because the claims are broadly drawn to a method of preventing an increase in the blood level of IFN-γ in a subject at risk of an elevated IFN-γ blood level due to (i) administration of a therapeutic agent or (ii) a disease condition, comprising orally administering any IFN-τ to the subject at a dosage of greater than about $5x10^8$ units to decrease the subject's IFN-γ blood level relative to the IFN-γ blood level in the absence of IFN-τ administration.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite because claim 1 recites a method of preventing an increase in the blood level of IFN-γ in a subject, but the subject already has an elevated IFN-g in the blood level and is administered IFN-τ to decrease the subject's IFN-γ blood level. The method cannot prevent an increase of IFN-τ if the increase of IFN-τ has already taken place.

The term "subject at risk" in claims 1-6 is a relative term which renders the claims indefinite. The term "subject at risk" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. For example, it is not clear if a subject at risk is a patient with a disorder or a normal patient.

The term "therapeutic agent" and "disease condition" in claims 1-6 are relative terms which render the claim indefinite. The term "therapeutic agent" and "disease condition" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. For example, it is not clear if a therapeutic agent encompasses antibodies, organic molecules, oligonucleotides, agonists, antagonists, etc.

The term "subject's symptoms" in claims 4-6 is a relative term which render the claims indefinite. The term "subject's symptoms" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. For example, it is not clear if symptoms encompass headaches, pain, blurry vision, or stress, etc.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting

rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the following claims in the indicated applications:

Application No.	Claims
10/346,269	1-31, 33-34, 36-37
10/592,162	21-25
10/825,068	1, 3, 4, 6, 8, 10, 11
10/825,382	1-7, 14-15
10/884,741	1-6, 8-10, 19-22
10/991,653	49-56
11/040,706	1-6, 8, 14, 18, 23-28, 30, 32, 33
11/078,608	1, 6-8
11/112,369	1, 17, 18
11/298,955	1-12
11/298,972	1-12
11/410,438	1-3

Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims are drawn to methods of administration of interferon tau (via oral administration or injection). The claims of the instant application recite the administration of interferon tau to prevent an increase in the blood level of IFN-γ in a subject. The claims in the other co-pending applications recite the administration of interferon tau or the administration of interferon tau to treat viral infection, cancer, autoimmune disorders, multiple sclerosis, or cardiovascular disorders or to stimulate IL 10. The instant method steps of oral administration of interferon-tau would inherently perform these activities. The prevention of an elevated IFN-γ blood level (as recited by the instant claims) would also inherently be occurring in the patient population of the other cases since the same product is being administered. It is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)).

Moreover, the applications recite "autoimmune disorder" or "MS" (which is an autoimmune disorder). The applications do not recite any further restrictions as to the patient population (ie. not at risk of having an elevated IFN-γ blood level). So, the patient population of the instant application (at risk of an elevated IFN-γ level) overlaps with the populations recited in the other applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the following claims of the indicated two U. S. Patents.

Patent No. Claims

7,083,782	1-3
7,105,154	1-4

Although the conflicting claims are not identical, they are not patentably distinct from each other because all three sets of claims are directed to methods of oral administration of interferon tau. The claims of the instant application recite the administration of interferon tau to prevent an increase in the blood level of IFN-γ in a subject. Claims of patent No 7,083,782 are directed to a method for treating multiple sclerosis (an autoimmune disorder) in a human subject comprising administering interferon tau to the subject. The claims of Patent No. 7,105,154 are directed to a method for treating a condition responsive to interferon tau therapy, wherein the condition is selected from an autoimmune condition, cancer, or a viral infection in a human subject comprising orally administering interferon-tau to the intestinal tract of the subject. The prevention of an increase in the blood level of IFN-γ in a subject (as recited by the instant claims) would also inherently be occurring in the patient population of the other cases since the same product is being administered. It is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Soos et al. (US Patent No. 6,060,450, filed on May 25, 1999).

The claims are drawn to a method of preventing an increase in the blood level of IFN-γ in a subject at risk of an elevated IFN-γ blood level due to (i) administration of a therapeutic agent or (ii) a disease condition, comprising orally administering IFN-τ to the subject at a dosage of greater than about $5x10^8$ units to decrease the subject's IFN-g blood level relative to the IFN-γ blood level in the absence of IFN-τ administration.

The IFN-τ is selected from ovine IFN-τ and bovine IFN-τ and has a sequence identified as SEQ ID NO;2 or SEQ ID NO:3. The subject in the method has an elevated IFN-γ level due to an autoimmune condition, and said orally administering continues during the period subject's symptoms. The autoimmune is multiple sclerosis or is a condition selected from the group consisting of Type I diabetes mellitus, rheumatoid arthritis, lupus erythematosus, psoriasis, Myasthenia Gravis, Graves' disease, Hashimoto's thyroiditis, Sjogren's syndrome, ankylosing spondylitis and inflammatory bowel disease.

Soos et al. teach a method of administering to a person an amount of interferon-tau to treat an autoimmune disease (columns 5-6; bottom of column 9 through column 10; columns 17-18, 21-22, claims 1, 8). Soos et al. disclose that the interferon-tau may be from any species that expresses interferon-tau, including ovine, bovine, and human (column 4, lines 1-10). The autoimmune condition is selected from the group consisting of rheumatoid arthritis, diabetes, multiple sclerosis, lupus, and psoriasis (column 22, claim 8). Moreover, Soos et al recite that the method of administering is via oral administration (column 22, claim 10) or via injection (column 21, claim 2).

The administration of interferon-tau will alleviate symptoms associated with an autoimmune disorder and also inherently decrease IFN-γ. It is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Soos et al. (US Patent No. 6,372,206, filed on March 15, 1996).

Soos et al. teach a method of administering to a person an amount of interferon-tau to treat an autoimmune disease (column 4, lines 26-47). In addition, Soos et al. disclose that interferon-τ is selected from ovine (column 31, claim 4) and has a SEQ ID NO:2 (column 31, claim 5; the amino acid sequence is disclosed in column 25) is identical to the SEQ ID NO:2 of the instant application.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
February 15, 2007

Bridget P. Bunner

BRIDGET BUNNER
PATENT EXAMINER